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510(K) Summary

Date: February 22, 2006

K060253

Submitted by: Lisa Simpson
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4326
Fax: 386-418-3607

Proprietary Name:
STERLING® Interference Screw HT
STERLING® Interference Screw ST

Common Name:
Screw, fixation, bone

Classification:
HWC, orthopedics panel

Code Section:
21 CFR 888.3040

Substantial Equivalence:
The STERLING® Interference Screw HT and STERLING® Interference Screw ST are substantially equivalent to predicate devices in materials, design, and function.

Description:
The STERLING® Interference Screw HT is machined from processed bovine cortical bone, with lengths ranging from 20 to 35mm and diameters ranging from 7 to 12 mm. The STERLING® Interference Screw HT is threaded and has an external squared-drive.

The STERLING® Interference Screw ST is machined from processed bovine cortical bone, with lengths ranging from 20 to 35mm and diameters ranging from 7 to 12 mm. The STERLING® Interference Screw ST is threaded and has an internal hex-drive.

Intended Use:
The STERLING® Interference Screw ST is used to provide interference fixation of femoral and/or tibial tunnels in anterior cruciate ligament reconstruction using a soft tissue graft, and fixation during posterior cruciate ligament reconstruction utilizing a soft tissue graft.

The STERLING® Interference Screw HT is used to provide interference fixation in anterior cruciate ligament reconstruction using a bone-tendon-bone graft, and fixation during posterior cruciate ligament reconstruction utilizing a bone-tendon-bone graft.

Summary of Technological Characteristics:

The STERLING® Interference Screw HT and the STERLING® Interference Screw ST have materials, design and function equivalent to predicate devices. The source of bovine bone used in the manufacture of STERLING® Interference Screw HT and STERLING® Interference Screw ST is a closed herd located in the U.S.A. The STERLING® Interference Screw HT and STERLING® Interference Screw ST have been shown to remodel comparably to allograft in an animal model.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2006

Ms. Lisa Simpson
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615

Re: K060253
Trade/Device Name: Sterling® Interference Screw HT, Sterling® Interference Screw ST
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 1, 2006
Received: February 1, 2006

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060253

Device Name: STERLING® Interference Screw HT
STERLING® Interference Screw ST

Indications for Use:

The STERLING® Interference Screw ST is used to provide interference fixation of femoral and/or tibial tunnels in anterior cruciate ligament reconstruction using a soft tissue graft, and fixation during posterior cruciate ligament reconstruction utilizing a soft tissue graft.

The STERLING® Interference Screw HT is used to provide interference fixation in anterior cruciate ligament reconstruction using a bone-tendon-bone graft, and fixation during posterior cruciate ligament reconstruction utilizing a bone-tendon-bone graft.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number _____